MEDICAL DEVICE
MANUFACTURERS
ASSOCIATION

August 31, 2000



Dockets Management Branch (HFA-305)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 98N-0331: Draft Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997**

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment upon this Food and Drug Administration (FDA) draft guidance for the further implementation of the third-party review program. MDMA is a national trade association based in Washington, D.C., representing 130 independent manufacturers of medical devices, diagnostic products, and health care information systems. As such, MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products to the market.

MDMA continues to support strongly the third-party review program as an adjunct to the traditional FDA premarket review program. MDMA helped to shape the vision of the third-party program through its *Blueprint for Reform of the FDA's CDRH*, published in 1995, and we worked for this program's inclusion in the FDA Modernization Act of 1997 (FDAMA). Also, when Commissioner Henney joined the FDA not long after the passage of FDAMA, her statements during her Senate confirmation hearings suggested that the FDA would embrace third-party review as a means to broaden the agency's science base. In our opinion, third-party review provides Commissioner Henney and the FDA with an important tool to do that through leveraging outside scientific rescues.

A key to the success of the third-party review program is its expansion. MDMA is encouraged by the FDA's expanded list of eligible devices that includes all devices eligible under the provisions of FDAMA. MDMA believed that limiting the use of the program through, for instance, requiring the existence of guidance documents for the products in question was too restrictive and not in accordance with Congressional intent under FDAMA. In the future, MDMA would like to reserve the right to submit to the FDA for consideration of eligibility under third-party review other devices that we believe fit into the eligibility requirements outlined in FDAMA and that might not already be included.

So far, our limited experience as an industry with third-party review has been positive. Third parties have been fair and responsive and have been willing to commit to maximum in-house

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review times. The FDA, for its part, has kept its supervisory review time short once the agency receives third parties' recommendations on particular devices.

Unfortunately, this program has been underutilized so far by the medical device industry, in large part because the FDA has streamlined its own review processes. However, MDMA also believes industry underutilization of third-party review can be attributed in part to the manner in which FDA has implemented this program. Therefore, we appreciate this opportunity to provide specific comments on ways the FDA could make this program more beneficial for the medical device industry and more valuable for the FDA.

***Specific Comments***

- Qualifications for eligible third parties: MDMA does not dispute the imposition of a required number of successful 510(k) third-party reviews, as outlined in the draft guidance, for an Accredited Person to have completed before reviewing devices with no device-specific review guidance. However, MDMA disagrees with the FDA's proposal that one of these reviews must be within the same medical specialty area as the device the Accredited Person now intends to review. This added restriction would drastically hamper third-party reviewers' ability to review devices without a device-specific review guidance, thus not "expanding" the program as it has been intended. Accredited Persons have already been accredited by FDA to review each medical specialty and device they applied to be eligible to review. This accreditation process should be sufficient to evaluate an Accredited Person's ability to review products without a guidance document.

- "Contact Meeting" Requirements: In this draft guidance, FDA outlines requirements for third-party reviewers to contact the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief before initiating a 510(k) review for a Class II device without a device-specific guidance. Once again, MDMA believes that this requirement adds another restrictive layer to the third-party review process, especially since the FDA does not propose a timeframe in which the FDA would respond to an Accredited Person's inquiry.

- Access to Internal Documents: MDMA believes the facilitation of an open working relationship between the FDA and the third-party reviewers would obviously contribute to better and quicker reviews. Therefore, the FDA should provide third-party reviewers with access to all internal FDA documents related to the review of these devices. Such access would assist third-party reviewers in carrying out their work, and would symbolize the FDA's intent to leverage outside resources in pursuit of its scientific mission.

- Accredited Persons Continuing Training: MDMA supports the training of third-party reviewers. We encourage the FDA to develop some sort of "continuing training" program through a partnership between third-party reviewers and the FDA. We do not intend to suggest a program that would be cumbersome or burdensome for the FDA, but we believe a

program would help keep all parties abreast of the latest scientific developments and the ongoing re-engineering of the premarket review process. MDMA would be willing to be a partner in these efforts.

- Review of the Success of the Program: MDMA believes that the FDA needs to set a reasonable timeframe for judging the overall success of this expanded third-party review program. In our opinion, the FDA's suggestion to review the program after 12 months does not provide such a timeframe. Once this draft is finalized, several months will be necessary for the third-party reviewers and the industry to come up to speed on this program and submit applications for review. In good faith, MDMA recommends that the FDA extend the timeframe for evaluation and review of this program to at least 24 months from the date that this draft guidance is finalized.

Our federal government and the private sector have a long history of collaborating to further our society's knowledge and advancement of science, and the FDA's expansion of third-party review should enable the FDA to follow in this tradition of leveraging outside scientific resources in the best interest of the public health. However, the success of third-party review depends upon the dedication of FDA officials, scientists, and reviewers to treating the third parties as partners in the regulatory process. We hope, then, that our comments will contribute to strengthening this partnership and the third-party review program at the FDA.

Very sincerely yours,

Mary Lacey Reuther

Mary-Lacey Reuther
Deputy Executive Director

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